

## REMARKS

### I. Status of the Claims

Claims 1-9 and 52 were pending in the parent application and rejected. Claims 53-56 have been added herein. Claims 10-29 and 32-51 have been canceled previously. Claims 1-9 and 52 were rejected.

### II. Amendments

Independent claims 53 and 56 have been added. Support for these claims is found throughout the application, with particular reference to page 11, lines 8 through 16 defining "preliposome-lyophilate" and page 10, line 25 through page 11, line 7 defining "submicron-reconstitute."

Claims 54 and 55, dependent on claim 53, are supported throughout the application with particular reference to page 12, lines 1 through 7. No new matter has been added.

For the Examiner's convenience, a complete listing of marked up (Appendix A) and pending claims (Appendix B) showing changes is appended hereto.

### III. 35 U.S.C. §112, Second Paragraph

Applicants wish to address the clarity of claims drawn to compositions comprising "submicron-reconstitute preliposome-lyophilate." Both terms are explicitly defined in the specification. The Examiner's attention is respectfully drawn to:

- page 11, lines 8 through 16 defining "preliposome-lyophilate" and
- page 10, line 25 through page 11, line 7 defining "submicron-reconstitute"

Reference is made to MPEP §608.01(o). Definitions are properly placed within the specification, and need not be reiterated within the claims.

In an excess of caution, along with new claims 53-55, claim 56 is presented. Claim 56 is drawn to a composition of submicron-reconstitute preliposome-lyophilate as defined in the invention, but without *in haec verbis* use of those terms.

#### **IV. Rejection Under 35 U.S.C. §102(b)**

Claims 1 and 52 were rejected under 35 U.S.C. § 102(b), as anticipated by U.S. Patent 4,950,432 to Mehta *et al.* (“Mehta ‘432”). This rejection is respectfully traversed.

Applicants’ claim limitations are not process limitations excludable from consideration of the product claims. Limitation to an “aqueous/t-butanol solvent system,” as claimed, is clearly a cognizable limitation to a product-by-process claim.

Limitations denominated as “process” limitations are held not patentably distinguishing *only* in cases where *the product is not patentably distinguishable*. See, *Ex parte Edwards et al.* 231 USPQ 981 (POBAI 1986) citing *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985). In contrast, the limitations at issue in the instant matter define a patentably distinguishable product.

Addressing two of the limitations, attention is respectfully drawn to their product defining function – defining the claimed product *as manufactured*:

- “facile-reconstitute” refers to a distinguishing characteristic of the product. The distinguishing *product* characteristic is the facility of reconstitution -- a physical property

of the lyophilate *per se*. This characteristic is presented at specification page 19, lines 16-20 and page 20, lines 21-23.

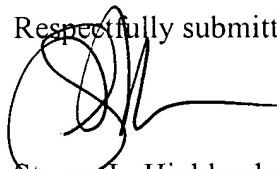
- “submicron-reconstitute” refers to a distinguishing characteristic of the product. The distinguishing *product* characteristic is the size of liposomes which appear upon reconstitution. The differentiating aspect becomes manifest within a process – reconstitution – but this does not alter its presence in the product *per se*. This aspect is found at specification page 8, lines 23 and 26, page 19, line 25 through page 20, line 21, and FIGS. 2 and 3.

Applicants respectfully submit that such limitations cognizable in the context of an apparatus claim definition. Applicants maintain that *In re Mattison and Swanson*, 184 USPQ 484, 485 (CCPA 1975) is controlling.

V. Conclusion

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to the effect is earnestly solicited. Should Examiner Kishore have any questions regarding this submission, a telephone call to the undersigned is respectfully requested.

Respectfully submitted,



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**APPENDIX A: MARKED UP COPY OF CLAIMS**

53. (New) A preliposome-lyophilate constituting liposomes of submicron size (diameter) distribution upon reconstitution into liposomes in the presence of aqueous solution.
54. (New) The preliposome-lyophilate of Claim 53 comprising a non-lipid surfactant.
55. (New) The preliposome-lyophilate of Claim 54 wherein said non-lipid surfactant is selected from the group consisting of polyoxyethylene sorbitan monolaurate having a molecular weight of approximately 1300 and polyoxyethylene sorbitan monooleate having a molecular weight of approximately 1350.
56. (New) A non-aqueous material that will form liposomes upon addition of aqueous solution wherein said liposomes constitute submicron size (diameter) distribution upon reconstitution into liposomes in the presence of aqueous solution.